



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,959	10/13/2000	James A. Bibb	600-1-257 CIP	8464
20583 7590 05/18/2004			EXAMINER	
JONES DAY			SHUKLA, RAM R	
222 EAST 41ST ST				
NEW YORK, NY 10017			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

219

Office Action Summary

Application No.

09/687,959

Applicant(s)

BIBB ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16 and 18-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 13 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-17-2003 has been entered.
2. Applicants' amendments and response filed 10-17-03 have been received and entered.
3. It is noted that during a telephonic call by the Examiner, applicants indicated that they had filed RCE and other documents on 10-17-03. Applicants faxed a copy of the amendment and other documents along with a copy of the stamped postcard from OIPE ON 2-6-04.
4. Claim 17 has been cancelled. New claim 23 has been entered.
5. Claims 16 and 18-23 are pending and under consideration.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 18, 19, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claimed invention is directed to a method of treating drug abuse in an individual by administering an agent that inhibits phosphorylation of Thr75-DARP-32.

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. When the claims are analyzed in light of the specification, instant invention recites a genus, an agent that has a certain activity-inhibiting a reaction or binding to a molecule modulator. While the art list two classes and a compound, the specification does not teach what would be the complete structure of a representative number of species of the genus agent.

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics, such as specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other identifying characteristic is that the agent would inhibit an activity or bind to a protein. However, the specification does not disclose any identifying characteristic as to how an artisan would have differentiated an inhibitor from other members of the genus or what would be the common characteristic of compounds that inhibited the reaction and bound to the protein as recited. Alternatively, the specification does not describe as to what would be the identifying characteristic of an inhibitor that would distinguish it from an agent that would bind to protein or what cross blood brain barrier.

Accordingly, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that the applicant is in possession of the broad genus of the agents at the time the application was filed. Thus it is concluded that the written description requirement is not satisfied for the claimed genus.

7. Claims 16 and 18-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating dopamine dysregulation or drug abuse in an individual comprising administration to the individual an agent that is a member of a compound selected from the group consisting of an indirubin and a paullone, wherein said agent binds to Cdk5 and

Art Unit: 1632

such binding results in the inhibition of the phosphorylation of Thr75-DARP-32 and wherein said agent can cross the blood brain barrier, is not enabling for practicing the claimed method wherein any agent that inhibits phosphorylation or any agent that binds to Cdk5, for reasons of record set forth in the previous office actions of 3-29-02 and 12-18-02. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that the total lack of enablement rejection of claims 16 and 18-22 and the newly presented claims 23 has been changed to a scope rejection in view of applicants amendment to the claims and arguments. However, the claims as instantly presented are not enabled for their full breadth for reasons of record discussed in the previous office action of 3-29-02 and 12-18-02.

Response to Arguments

Applicant's arguments filed 10-17-2003 have been fully considered but they are not persuasive to withdrawn all the grounds of rejection. It is noted that no arguments were presented in the applicants response regarding the rejection except for discussion of Jaber et al (Ref. V) and misapprehension of a statement by the Patent office and the arguments cite page 4 of the office action of December 18, 2002. However, it is not clear what information was represented since Dr. Fienberg is the author of the Science review article and the declaration and that's what was addressed in the cited office action. Applicants' arguments that brain slice model is not a standard cell culture model but uses cellular structure taken directly from the animal are well taken but still brain slice does not represent a brain in an animal therefore it can not be a model for a disease or for an in vivo physiological state of brain in an animal.

8. Allowable subject matter:

If the instantly presented claims are amended to reflect the scope of enabled invention set forth in the enablement rejection, claims would be allowable.

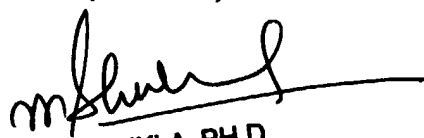
Art Unit: 1632

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER